WINSTON & STRAWN LLP
The Legal Center
One Riverfront Plaza, Suite 730
Newark, New Jersey 07102
(973) 848-7676
James S. Richter

*Attorneys for Plaintiffs, West-Ward Pharmaceuticals Corp.
and Hikma Pharmaceuticals LLC*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

WEST-WARD PHARMACEUTICALS CORP. and HIKMA PHARMACEUTICALS LLC,	Honorable
Plaintiffs,	Civil Action No.:
v.	
PAR PHARMACEUTICAL INC.	**COMPLAINT FOR PATENT INFRINGEMENT**
Defendant.	

Plaintiffs West-Ward Pharmaceuticals Corp. ("West-Ward") and Hikma Pharmaceuticals LLC ("Hikma") (together, "Plaintiffs"), for their Complaint against Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action arises from Par Pharmaceutical's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Hikma's Mitigare® (colchicine) 0.6 mg capsule, before the expiration of U.S. Patent No. 8,927,607 (the "'607 patent," attached as Exhibit A), throughout the United States, including in New Jersey.

PARTIES

3. West-Ward Pharmaceuticals Corp. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724-2206.

4. Hikma Pharmaceuticals LLC is a company organized and existing under the laws of Jordan, having a principal place of business in Bayader Wadi Seer, P.O. Box 182400, Amman 11118, Jordan. West-Ward is the authorized U.S. agent for Hikma.

5. Upon information and belief, Par Pharmaceutical is incorporated under the laws of Delaware, and has a principal place of business at One Ram Ridge Road, Chestnut Ridge, NY, 10977. Upon information and belief, Par Pharmaceutical, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100071541, and has appointed Thomas Haughey, 300 Tice Boulevard, Woodcliff Lakes, NJ 07677, as its registered agent to accept service of process. Upon information and belief, Par Pharmaceutical, Inc. is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5004032.

JURISDICTION AND VENUE

6. Hikma seeks to enforce its federal patent rights under Title 35, United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

7. This Court has personal jurisdiction over Par Pharmaceutical because, among other reasons, it has substantial and continuous contacts with the state of New Jersey, and because it has committed the acts of patent infringement alleged herein in New Jersey. Indeed, Par Pharmaceutical has previously stipulated to or not challenged that the District of New Jersey has jurisdiction over it (e.g., Case Nos. 15-cv-1454, 14-cv-2065, and 12-cv-6738), and Par Pharmaceutical has availed itself of the rights, benefits and privileges of this Court by filing at least two complaints for patent infringement in the District of New Jersey as recently as in June, 2016 (e.g., Case Nos. 3:16-cv-3676 and 2:16-cv-2290).

8. Upon information and belief, Par Pharmaceutical is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

9. This Court has personal jurisdiction over Par Pharmaceutical by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury in New Jersey to Hikma and to West-Ward, a New Jersey resident corporation. For example, upon information and belief, Par Pharmaceutical is actively preparing to make the proposed generic copies of Mitigare® (colchicine) that are the subject of Par's ANDA, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

THE FDA MARKETING APPROVAL PROCESS

11. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

12. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355. Alternatively, an applicant can use the 505(b)(2) "paper NDA" process for new drugs that are similar but not identical to existing ones. This process permits the applicant to rely on existing studies for a previously approved drug of the applicant's choosing while supplementing the application with new studies and data to support a safety and effectiveness determination. *Id*. § 355(b)(2).

13. An NDA or a paper NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

14. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

15. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an ANDA under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

THE PATENT-IN-SUIT

16. The United States Patent & Trademark Office ("USPTO") duly and legally issued the '607 patent, titled "Methods of colchicine administration," on January 6, 2015. (Attached as Exhibit "A".) The '607 patent lists Murray Ducharme as an inventor.

17. Hikma Pharmaceuticals LLC lawfully owns all right, title, and interest in the '607 patent, including the right to sue and to recover for past infringement.

THE MITIGARE® PRODUCT

18. Plaintiffs sell Mitigare® (colchicine) in the United States pursuant to a New Drug Application ("NDA") No. 204820 that has been approved by the FDA. Mitigare® is a colchicine 0.6 mg capsule indicated for the prophylaxis of gout.

19. In accordance with 21 U.S.C. § 355(b)(1), the '607 patent is listed in the Orange Book in connection with NDA No. 204820 as a patent "with respect to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Mitigare®.

PAR PHARMACEUTICAL'S ANDA SUBMISSION

20. By letter dated July 26, 2016 ("Par Notice letter"), Par Pharmaceutical notified Plaintiffs that it had submitted to the FDA its ANDA No. 208678 ("Par ANDA") for Par Pharmaceutical's colchicine capsules, a drug product that is a generic version of Mitigare® (colchicine) ("Par's ANDA Product").

21. Upon information and belief, the purpose of the Par ANDA was to obtain marketing approval from FDA to engage in the commercial manufacture, use, and/or sale of Par's ANDA Product prior to the expiration of the '607 patent.

22. In the Par Notice Letter, Par Pharmaceutical notified Plaintiffs that, as part of its ANDA, Par included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '607 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of Par's ANDA Product.

23. The use of Par's ANDA Product is covered by one or more claims of the '607 patent.

24. Par Pharmaceutical had knowledge of the '607 patent when it submitted the Par ANDA.

25. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Par Notice Letter, which Plaintiffs received on or about July 27, 2016.

COUNT 1: INFRINGEMENT OF THE '607 PATENT

26. Paragraphs 1 to 25 are incorporated as if fully set forth herein.

27. The use of Par's ANDA Product is covered by one or more claims of the '607 patent.

28. The submission of Par's ANDA No. 208678 with a Paragraph IV certification regarding the '607 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Par's ANDA Product before the expiration of the '607 patent constitutes infringement of one or more of the claims of the '607 patent under 35 U.S.C. § 271(e)(2).

29. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Par's ANDA Product before the expiration of the '607 patent would infringe one or more claims of the '607 patent under 35 U.S.C. § 271.

30. Unless enjoined by this Court, Par Pharmaceutical intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Par's ANDA Product immediately and imminently upon approval of the Par ANDA.

31. Unless enjoined by this Court, Par Pharmaceutical intends to, and will, actively induce infringement of the '607 patent when the Par ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

32. The forgoing actions by Par Pharmaceutical prior to the expiration of the '607 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) or (c).

33. Par Pharmaceutical acted without a reasonable basis for believing that it would not be liable for infringing the '607 patent, actively inducing infringement of the '607 patent, and/or contributing to the infringement by others of the '607 patent.

34. Unless Par is enjoined from infringing the '607 patent, actively inducing infringement of the '607 patent, and/or contributing to the infringement of the '607 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

35. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Par's ANDA No.

208678 to be a date which is not earlier than the date on which the ’607 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

36. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. Judgment in favor of Plaintiffs and against Defendant;

b. Judgment that the ’607 patent is valid and enforceable;

c. Judgment that Par Pharmaceutical has infringed, literally and/or by the doctrine of equivalents, one or more claims of the ’607 patent by submitting ANDA No. 208678, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Par’s ANDA Product in the United States will constitute infringement, contributory infringement, or actively inducing infringement of the ’607 patent;

d. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 208678 relating to Par’s ANDA Product shall be not earlier than the date of expiration of the ’607 patent, or any later date of exclusivity to which Hikma is or becomes entitled;

e. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., restraining and enjoining Par Pharmaceutical and its officers, partners, agents, attorneys, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in privity or concert with it, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States Par's ANDA Product, and any product that is similar to or only colorably different from that product, and from infringing, contributorily infringing, or inducing others to infringe the '607 patent, before the expiration of the '607 patent or any later date of exclusivity to which Hikma is or becomes entitled;

f. Damages or other monetary relief, including pre-judgment and post-judgment interest, to the extent that Par Pharmaceutical engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States Par's ANDA Product, or any product that infringes the '607 patent, or contributes to or actively induces infringement of the '607 patent, before the expiration of the '607 patent or any later date of exclusivity to which Hikma is or becomes entitled;

g. A declaration that this is an exceptional case and an award of reasonable attorney's fees and expenses to Plaintiffs pursuant to 35 U.S.C. § 271(e)(4) and 285;

h. Plaintiffs reasonable costs and expenses incurred in bringing and prosecuting this action; and

i. Such other and further relief as the Court deems just and appropriate.

WINSTON & STRAWN LLP
Attorneys for Plaintiffs West-Ward Pharmaceuticals Corp. and Hikma Pharmaceuticals LLC

By: s/ James S. Richter
James S. Richter
jrichter@winston.com

Dated: September 8, 2016

OF COUNSEL:

Samuel S. Park
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601-9703
(312) 558-5600
spark@winston.com

Charles B. Klein
Jovial Wong
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
cklein@winston.com
jwong@winston.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the within action is not the subject of any other action pending in any Court, or of any pending arbitration or administrative proceeding.

/s/ James S. Richter
James S. Richter

Dated: September 8, 2016

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1(d)(3)

Pursuant to Local Civil Rule 201.1(d)(3), I hereby certify that this action is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

/s/ James S. Richter
James S. Richter

Dated: September 8, 2016